10. REQUEST FOR CONSTRUCTIVE ASSISTANCE

Applicant has made diligent effort to write the claims of this application in allowable condition. If for any reason the claims are not believed to be in full condition for allowance, Applicant respectfully requests the constructive assistance of Examiner pursuant to MPEP 707.07(j), and 706.03(d) in order that this application be placed in allowable condition as soon as possible.

REMARKS

3. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 FIRST PARAGRAPH.

Claim 1 was rejected under 35 U.S.C. 112, first paragraph, stating that the specification, while being enabling for treating an infectious disease caused by drug resistant strain of bacteria such as Staphylococcus aureus with pepper, does not reasonably provide enablement for treating other infectious diseases caused by other types of drug-resistant strains of bacteria such as Streptococcus or Clostridium difficile with pepper. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A practitioner of the art being of Ph.D or M.D. qualification, and so enabled to properly treat a staph infection as Examiner has affirmed, would simply apply the same medication to treat a Strep, or Clostridium infection, so enabling the desired endeavor.

The spec is clear that the pepper compounds are broad spectrum in nature, and has provided a very strong rational association in structure. Think Penicillin. They tried it on everything infection and it changed the world in it's day.

If results fall short of a holy grail, the practitioner is further enabled to explore other disclosed candidates that may show greater promise.

In either case, the practitioner is enabled, and practicing the invention as claimed.

The flaw that haunts this examination, is the presumption and assertion that prior art failures somehow prove that the invention as claimed does not work in most cases unless proven otherwise.

Examiner citation of In re Wands 8 USPQ2d 1400 (Fed. Cir., 1988) with regard to undue experimentation is not a valid reference here and should be withdrawn.

Claims 4 and 7 were rejected as failing to comply with the written description requirement, as the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. That practitioners of the art cannot immediately envision the invention, and are not reasonably lead to a particular species.

This rejection is yet again traversed.

The spec contains length discussion of chemical structures and associations, in vitro screens, and medical case studies to support a general theory to enable practitioners to immediately envision, and make and use the invention as claimed.

As before, a practitioner of the art is an individual of Ph.D or M.D. qualification. To suppose that such individuals given the entire disclosure cannot reasonably practice the invention is plainly absurd.

To suppose that such persons cannot understand terms like **bacterial infection and a pepper** is to assert that practitioners of the art are anything but educated.

Applicant submits that the instant spec is compliant with Examiner cited cases Fujikawa v. Wattanasin, 9 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) and In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). that such cases do not form a proper basis for rejection and should be withdrawn.

Applicant shall reiterate from past responses with regard to this matter:

It is clear from the specification that the pepper compounds are broad-spectrum antimicrobials among other things. The specification has disclosed other therapeutic properties of these same compounds beyond antibacterial, and has incorporated by reference other patents, which also disclose broad-spectrum antimicrobial properties to include antifungal properties and wart

treatment. See Abstract (p.19), Specification (p. 5.3.).

The instant specification further discloses more than seven specific cases, and referenced several other cases having been successfully treated with extracts of differing pepper plant species, differing solvents, and differing conditions, all with an astounding, and unprecedented level of effectiveness as compared to what practitioners of the art might expect with prior art treatments.

Clinical demonstrations of extracts of red pepper, black pepper, ginger, paprika, and isolated capsaicin using water, alcohol (ethanol, isopropal), acetone, pure oleoresin and others used separately and in combination against an array of microbes and types of microbial infection are found within the specification.

As such, Applicant asserts that the specification provides sufficient representative species to claim any genus as to plant source, type of solvent for extraction, and type of bacterial infection being treated, and that the inventor was in possession of the claimed invention as of the filing of the application.

As such, all rejection of the claims 4, and 7 as to failure of the specification to comply with the written description requirement is not proper and should be withdrawn with allowance of the claims 4, and 7 along with their appended dependant claims.

The patent specification is explicit as to specific formulations used in actual case studies.

A person skilled in the art is thereby enabled to both produce, and apply any of the formulations toward the treatment of diseases as specifically described, or to those related.

Beginning with production of a crude extract of pepper; a very simple, quick, and inexpensive procedure, a practitioner is at once well equipped with a remarkably effective medical treatment that is broad-spectrum in nature. From there, a practitioner has the further option of isolation or refinement of chemical components of the extract in order to optimize use toward more specific conditions, if so desired.

FURTHER STILL, it is important to note that the terms and phraseology at issue: **"...infectious diseases caused by drug-resistant strains of bacteria, bacterial infections in a human or animal host, solvent extraction of a component of a pepper plant"** found in the claim preamble serve to define

to practitioners of the art the scope or field(s) encompassed, and are not unique to the instant invention.

Herbalists, organic chemists, drug discovery scientists, and pharmacologists ect. easily understand what a "... solvent extraction of a component of a pepper plant..." entails in view of the written disclosure of the instant invention.

Physicians, Veterinarians, and their associated technicians understand what a bacterial infection is in a patient (host). They further understand that when such a patient (whether human or animal) does not respond adequately to (other art) drug treatment for such a bacterial infection, that the possibility exists that the particular strain of bacteria causing the disease is for some reason able to resist the drug being administered. This unfortunate dilemma often leads to far more serious illness and even death, and is being reported as increasing in frequency at an alarming rate making it a major health concern.

Articles of such reports have been a mainstay in newspapers, news broadcasts, non-techical magazines, and other general public publications for at least the last decade. The majority of people on the street are aware of this health care crisis, not to mention practitioners of the art.

Drug companies are spending 100's of millions of dollars enlisting a broad array of researchers in hopes of finding solutions to drug-resistant bacteria with only disappointing results.

Applicant submits that the written specification is enabling to practitioners of the art to make and use the invention, to ascertain the scope of the invention, that the Applicant was in possession of the invention at the time the application was filed, and that all requirements related to species/genus identification are satisfied in view of the prior Examiner cited Fujikawa v. Wattanasin, 9 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) and In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Further, that in the interest of being concise, the specification need not, and should not devote space to defining terms and phases already well understood to practitioners of the art.

4. AMENDMENT OF CLAIMS IN RESONSE TO REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH.

Claims 21 and 22 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claims 21 and 22 phrase "...said equivalent..." no longer has an antecedent basis in independent claim 7 upon deletion of the phase "or an equivalent".

Applicant does not contest the above Examiner statement. However, Applicant welcomes a recommendation from Examiner as to acceptable phraseology that would restore like antecedent basis to claims 21 and 22 that was lost upon deletion of the phase "or an equivalent" from claim 7 that occurred in response to Examiner requirement in the prior Office letter.

What would Examiner suggest as a replacement?

Please advise.

With regard to Examiner recommendation to rewrite claim 17 into independent claim format, Applicant requests to first resolve the lack of antecedent basis issue of claims 21 and 22 above.

Otherwise, it may become necessary to return to the "or an equivalent" claim phrase?

5. TRAVERSE OF REJECTION OF CLAIM 4 UNDER 35 USC SECTION 102

Claims 4 was rejected as being anticipated by newly cited Gal, "Capsicidin; a new compound with antibiotic activity from condiment paprika", Zeitschrift fuer Lebensmittel-Untersuchung und-Forschung (1964), 124(5), pp. 33-6 who reported that a cold water extract/solvent extraction process involving paprika yielded "...an antibiotic concentrate "capsicidin", reported to be "...active against several yeasts and bacteria".

This rejection is traversed.

Claim 4 is directed toward treatment of bacterial infections in humans or animals using a phytoalexin derived from pepper.

The Gal cited reference does not specify the type of bacteria tested. Gal et. al. suspected that capsicidin was a saponin, but makes no mention of it being a phytoalexin as in claim 4. Nor does Gal et. al. suggest that capsicidin be used for medicinal or veterinary purposes.

As the cited Gal et. al. reference fails to identify all elements of the invention as in claim 4, Gal et. al. is not a proper reference under 35 USC Section 102 and should be withdrawn.

6. TRAVERSE OF REJECTION OF CLAIMS 7 - 16, & 18 - 20 UNDER 35 USC SECTION 103(a).

Claims 7-16 and 18-20 were rejected as being anticipated by newly cited references Gal et. al. and Chen et al., "Antibacterial properties of some spice plants before and after heat treatment:, Chinese Journal of Microbiology and Immunology, Vol. 18, No. 3, pp. 190-195 (Aug. 1985)

This rejection is traversed.

As above, the newly cited Gal et. al., reported that a cold water extract/solvent extraction process involving paprika yielded "...an antibiotic concentrate "capsicidin", reported to be "...active against several yeasts and bacteria".

However, Gal et. al. does not specify the type of bacteria wherein antibiotic properties were observed, and does not specify *Staphylococcus* as in independent claim 7.

Nor does Gal et. al. recommend that capsicidin be used as a medicinal or veterinary treatment as in claim 7.

The newly cited Chen et. al. reference reported levels of antibacterial activity and inactivity of various spice plants before and after boiling in water.

Included among the aforementioned spices was ginger, ginger root, sweet pepper, chili pepper, and brown pepper. Though a strain of *Staphylococcus aureus* was tested, it was not inhibited by those members of the ginger, or pepper group of spices, and therefore would suggest that these spices lack

antimicrobial properties, and hence would not be good candidates for development into medical treatments.

Chen et. al. reported that the ginger group could only inhibit *Micrococcus luteus*, and *Vibrio parahaemolyticus*: neither of which are pathogenic to humans or animals, and as would be expected, did not support or include a recommendation to develop such into a medical treatment as found in the claims.

Chen et. al. also reported that the pepper group was largely ineffective against most of the test organisms, however certain members could inhibit *V. parahaemolyticus* , which is not pathogenic to man or animals, and *Proteus vulgaris*, which may rarely cause urinary tract infection.

Chen et. al. would suggest, as with Gal et. al., do not suggest that pepper related compounds are a preferred candidate for medicinal use, and infact suggest the opposite.

As the newly cited references Gal et. al., and Chen et. al., both separately and in combination fail to suggest all the elements of the invention as claimed, this rejection of claims 7-16 and 18-20 under USC 35 Section 103(a) is not proper and should be withdrawn.

CLAIMS